

A stylized, light blue map of East Asia, including Japan, Korea, and parts of China and the Philippines, serves as the background for the slide.

JaCVAM Update

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JaCVAM, NIHS

A light blue background featuring a faint map of Japan. The title 'Contents' is centered at the top in a bold, dark blue font. Below it, a bulleted list of three items is displayed in the same font style. The map shows the main islands of Japan, including Hokkaido, Honshu, Shikoku, and Kyushu, with surrounding waters and smaller islands visible.

Contents

- **JaCVAM peer review**
- **Japanese or International Validation study**
- **6th World Congress**

Test Method Validation Process

Review Risk Assessment Methods

Research

Development

Pre-validation

Validation

Peer Review

Acceptance

Implementation

Japanese system by JaCVAM

Cooperation of JSAAE, JEMS

Oversight committee

Peer Review

Ad hoc committee for regulatory acceptance

Refer to ICCVAM Guideline

A stylized, teal-colored map of Japan is centered in the background. The map shows the four main islands: Hokkaido, Honshu, Shikoku, and Kyushu, along with several smaller islands. The text "JaCVAM Peer Review" is overlaid on the map.

JaCVAM Peer Review

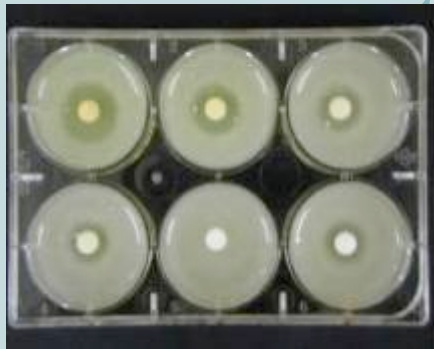
Human skin models for skin corrosivity tests

Current situation:

**Being Reported by Ad hoc committee
for regulatory acceptance**



**Battery system for prediction of
phototoxicity:
Yeast growth Inhibition phototoxicity
assay and
Red blood cell photohemolysis assay**



**Current situation:
Being Reported by
Peer Review Panel**

Human skin model for skin irritation tests

- **The Oversight committee is reporting of alternative to skin irritation testing using 3-dimensional cultured human skin models for peer review**
(Key words: ESAC, Japanese validation study, safety evaluation for cosmetic)

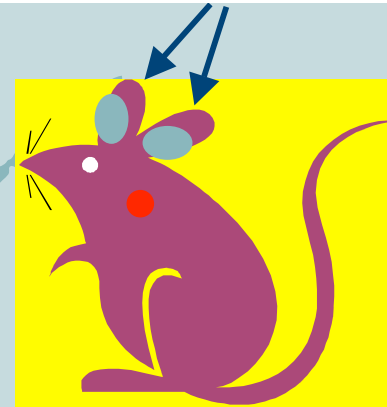


Peer review will start on this October

A stylized, light blue map of East Asia, including Japan, Korea, and Taiwan, serves as the background for the title. The map is rendered in a minimalist, silhouette-like style with a light blue color.

Japanese or International Validation

Validation study of LLNA-DA



Phase I:

Date: April-July/2006

Participated lab.: 10, 2-3 tests/Lab.

Purpose: Reliability and relevant

Chemical used: Total 12,
4-6 substances/Lab.

Phase: II

Date: December/2006-February/2007

Participated lab.: 7, 3 tests/Lab.

Purpose 1: Support of Phase I
validation

2: Transferability

Chemical used: Total 4

All validation study
are over.

Reporting of Validation
study is on going.

Conclusion on validation study of LLNA-DA

- A catch-up validation study performed **by 10 facilities**
- **Acceptable inter-laboratory reproducibility** for 10 of 12 chemicals
- **Sufficient relevance** compared to the LLNA

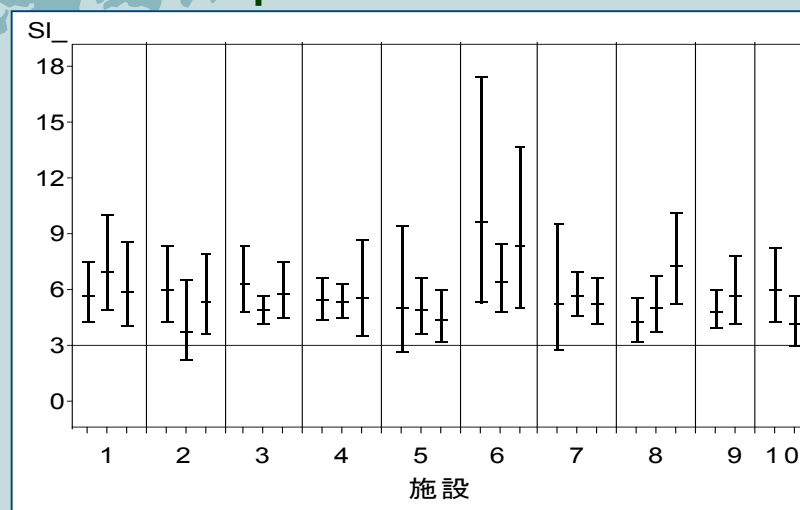
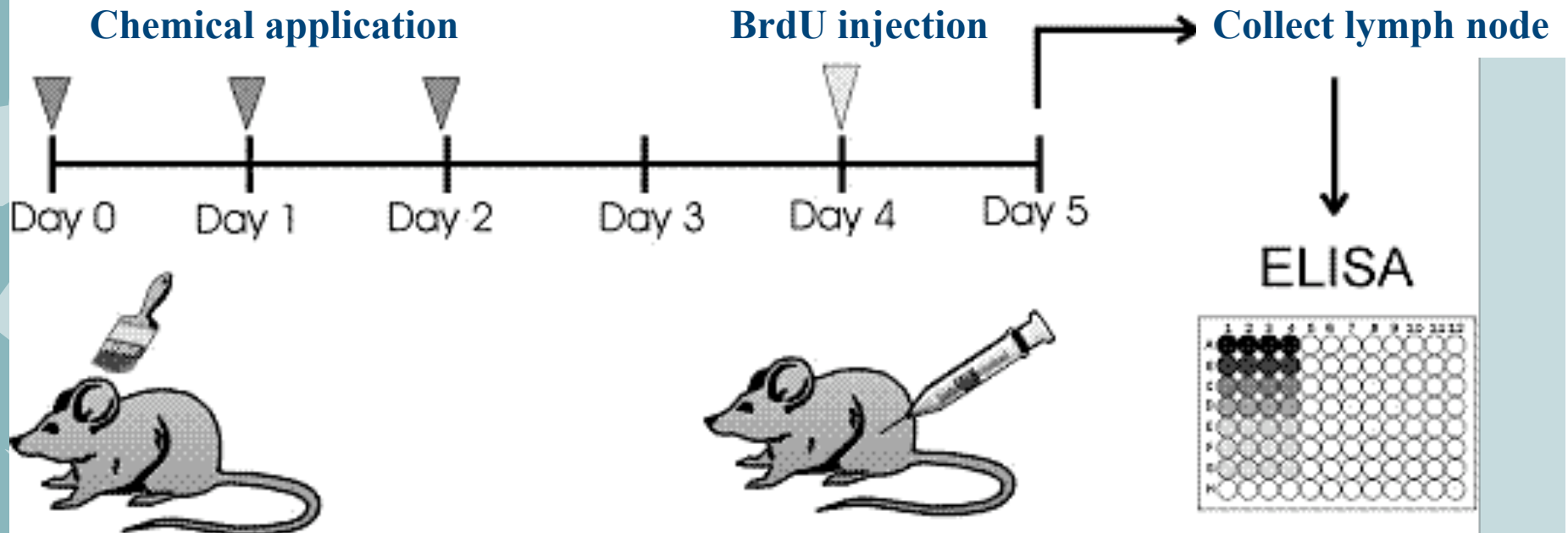


Fig. 1. SIs with 95% CI for the positive control
Positive control: Hexyl cinnamic aldehyde 25% AOO

Validation study of LLNA – BrdU



Phase I:

Date: October-December/2006
Participated lab. 9, 2-3 tests/Lab.
Chemical used: Total 12,
4-6 substances/Lab.

**Distribution of SI is
too large.
Revised SOP is on
going.**

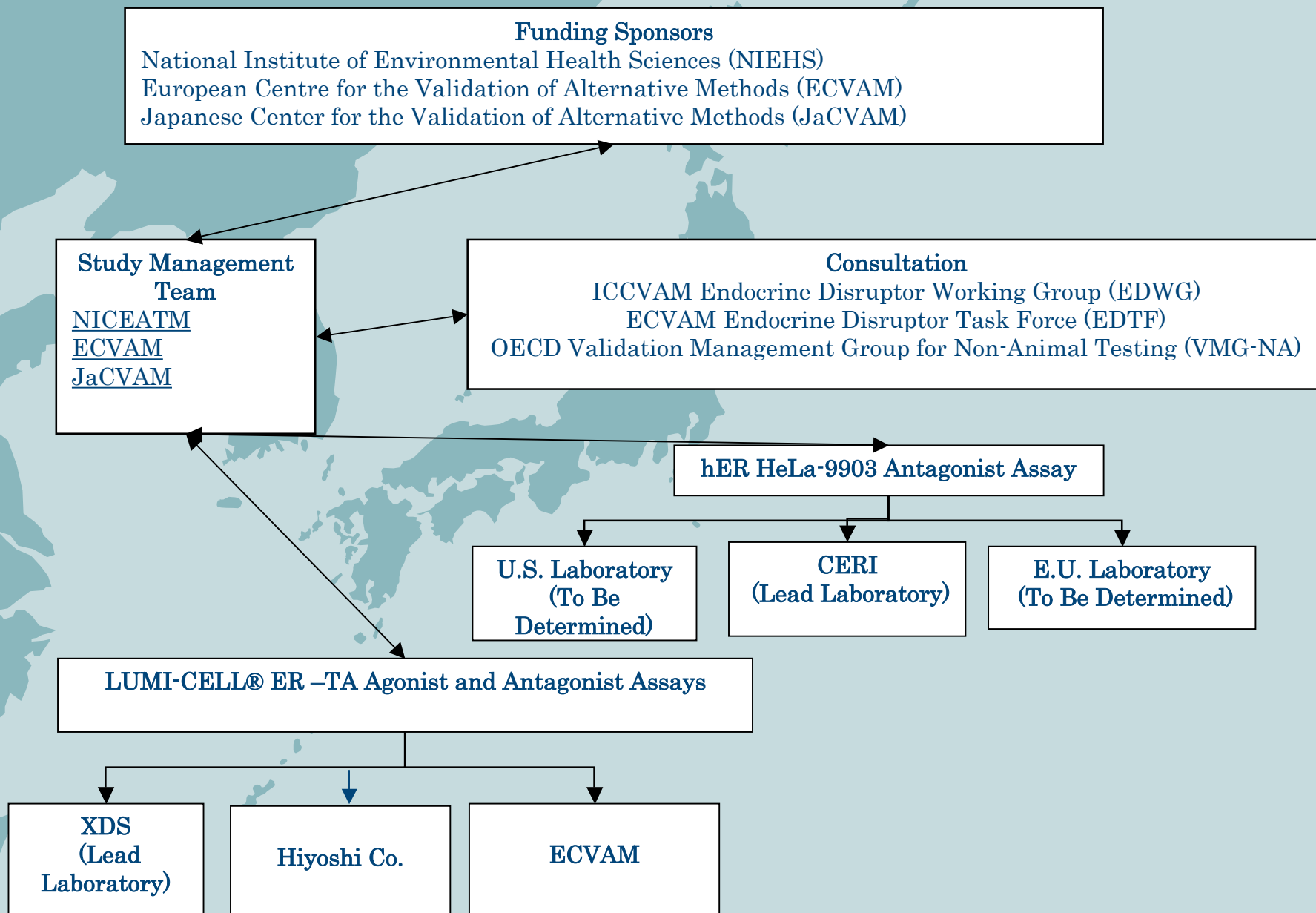


International validation study of reporter gene assays

Peer Review reports on OECD of hER HeLa-9903 Agonist Assay is waiting.

LUMI-CELL™ Estrogen Receptor Assay is under Phase I.

Organization of validation study on Estrogen receptor assay





International validation study of In vitro/in vivo Comet assay

Pre-validation study of *in vivo* is on going.

**The validation study of *in vitro* is planning
the kick-off workshop in 6th World Congress**

Organization of validation study on Comet assay

Study Management Team

M.Hayashi (NIHS)
L.Schechtmann (FDA)
R.Tice (NICEATM)
T.Hurtung (ECVAM)
Y.Uno (Mitsubishi)
H.Kojima (JaCVAM)

Consultation

B. Burlinson (Huntington)
Y. Sasaki (Hatanohe)
T. Ohmori (Kyoto Univ.): Statistician
N. Nakajima OECD Validation Management Group (VMG)

LOCAL MANAGEMENT TEAM

M.Homma (NIHS)
K.Morita (NIHS)
T. Asano(Nittodenko)
M.Nakajima (Biosafety Res. Ctr.)
Y. Yamakage(Hatano, Inst.FDSC)

Prevalidation of Comet Assays

Biosafety Res.
Ctr.

Hatano, Inst.,
Food and Drug
Safety Ctr.

Huntington
Life Sciences

Merck

BioReliance

Current validation and peer review correlated with JaCVAM

Test method	Material	Current activities
Phototoxicity	Yeast-RBC	Peer Review in progress
Skin sensitization	LLNA-DA	Validation is over
	LLNA-BrdU	Validation in progress
	h-CLAT	Pre-validation in progress
Corrosivity	Culture model	Regulatory acceptance in progress
Skin irritation	Culture model	Planning on Peer Review
Endocrine disrupter	Lumi-cell, CER-estrogen reporter assay	Validation in progress
Mutagenicity	Comet assay (in vivo or in vitro)	Validation in progress

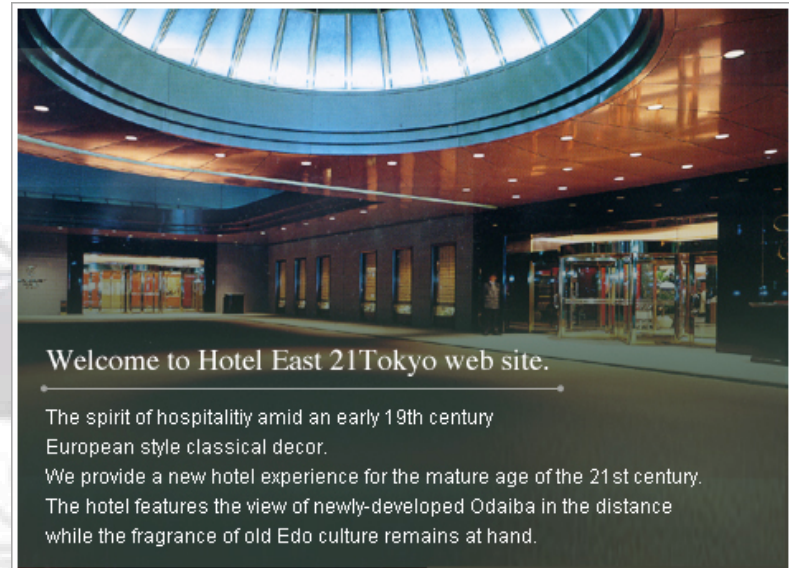
6th World Congress on Alternatives to Animal Experiments (WC6)



Data: August 21 – 25, 2007
Venue: Hotel East 21 Tokyo,
Tokyo, Japan

Co-Chair:
Yasuo Ohno, NIHS and
Horst Spielmann, ZEBET

Supported by
• **Japanese Society for the Alternative to**
Animal Experiments (JSAAE)
• **Japanese Council of Science (JCS)**
• **Alternative Congress Trust (ACT)**



Plenary Lectures

Judy McArthur Clark, Pfizer, USA

Julia Fentem, Unilever, UK

Paul Flecknell, Newcastle Univ., UK

Makoto Hayashi, NIHS, Japan

Special Lecture

Alan Goldberg, Johns Hopkins Univ., USA

Next President Special Lecture

Herman Koëter, EFSA, Italy

Animal Welfare Memorial Lecture

Michael Balls, FRAME, UK

Key Note Lecture

Horst Spielmann, ZEBET

Barones South Work,

Scientific and special session: 47

Open symposium for citizen

Luncheon seminar: 7

Poster presentation: Up 300 papers

Oral session for Young scientist: 22 papers



The sessions correlated with NICEATM or ICCVAM staff

Session

2-4	Public participation in decision-making on animal use	J.-K.-Eddy
4-4	Methodology of Validation study	A. Rispin
5-1	Acute toxicity	R. Tice
5-2	Eye irritation	W. Stokes
5-9	QSAR	D. Benz
5-10	Validation	M. Wind, W. Stokes, L. Schectman
5-12	In vitro comet assay	R. Tice
7-2	Biologicals	R. McFarland
9-2	International cooperation	W. Stokes
10-2	Risk assessment	M. Wind